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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,938	10/31/2001	Salvatore Albani	UCSD1360-1	8878

7590 06/28/2006

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,938	ALBANI ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-59,62-66 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *57 and 74* is/are allowed.

6)☒ Claim(s) *58,64 and 65* is/are rejected.

7)☒ Claim(s) *59, 62,63 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

1. Applicant's response and amendments received April 10, 2006 are acknowledged.

Claims 1-56, 60, 61, and 67-73 are canceled.

Claims 57 and 74 have been amended.

Claims 57-59, 62-66, and 74 are under examination in this office action as they read on peptides and compositions comprising peptides.

Claim Rejections - 35 USC § 102

2. The rejection of claims 57-59, 62, 66, and 74 under 35 U.S.C. 102(b) as being anticipated by Kurzik-Dumke (WO 98/32772, see entire document) has been withdrawn in light of applicant's amendments to independent claims 57 and 74 received April 10, 2006.

As a result of these amendments, the instant claims no longer recite the peptide taught by Kurzik-Dumke, namely SEQ ID NO:19 of the instant invention. Kurzik-Dumke does not teach peptides consisting of the remaining recited SEQ ID numbers, and therefore the rejection of record has been withdrawn.

Claim Rejections - 35 USC § 103

3. The rejection of claims 57, 59, and 62-65 under 35 U.S.C. 103(a) as being unpatentable over Kurzik-Dumke (WO 98/32772, see entire document) in view of Pillai et al. (US Patent No. 5,334,379, see entire document) has been withdrawn in view of applicant's claim amendments received April 10, 2006. Applicant has amended the claims to remove the recitation of SEQ ID NO:19, the peptide sequence taught by Kurzik-Dumke, and since neither the primary nor the secondary reference teach peptides consisting of the remaining sequences recited by SEQ ID number, the instant claims are not rendered obvious by their teachings.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 64 and 65 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

These claims recite compositions comprising one or more peptides that consist of the recited SEQ ID numbers and a cytokine that induces a pro-inflammatory response (claim 64) or an anti-inflammatory response (claim 65). The specification teaches that the genus of recited SEQ ID numbers includes peptides that induce pro-inflammatory responses and peptides that induce anti-inflammatory responses. Pro-inflammatory peptides induce the expression of IFNγ, with an example being the peptide consisting of SEQ ID NO:4 (see particularly paragraph 100 on page 39 and Figures 15-18), while anti-inflammatory peptides induce the expression of IL-10 as exemplified by the peptide consisting of SEQ ID NO:20 (see particularly paragraph 112 on page 49 and Figure 24B). The specification indicates that the peptides and compositions of the instant invention are to be administered to subjects to induce pro- or anti-inflammatory responses, yet a composition comprising a pro-inflammatory peptide and an anti-inflammatory cytokine comprises activities that cancel each other and such a composition would not induce a pro- or anti-inflammatory response upon administration. As such the claimed products appear to lack a specific and substantial utility or a well established utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 64 and 65 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 58 recites a chimeric polypeptide wherein a peptide of recited SEQ ID number is linked to a heterologous polypeptide. The specification teaches chimeric polypeptides wherein peptides disclosed by SEQ ID number are *operatively linked* to heterologous polypeptides such that the functions of the individual elements comprising the fusion polypeptide are maintained (see particularly paragraph 56 on page 21 of the specification). As such the phrase operatively linked has been defined by the specification to have a specific meaning. A chimeric polypeptide comprising linked sequences is broader in scope than a chimeric polypeptide comprising operatively linked sequences, and the specification does not disclose chimeric polypeptides comprising linked sequences. Claim 58 as originally filed recited operatively linked chimeric polypeptides. Applicant's amendment to the claim to delete the word "operatively" broadens the claimed invention, and this broadening is new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites a chimeric polypeptide wherein a peptide of recited SEQ ID number is linked to a heterologous polypeptide. The specification teaches chimeric polypeptides wherein peptides disclosed by SEQ ID number are *operatively linked* to heterologous polypeptides such that the functions of the individual elements comprising the fusion polypeptide are maintained (see particularly paragraph 56 on page 21 of the specification). As such the phrase operatively linked has been defined by the specification to have a specific meaning. A chimeric polypeptide comprising linked sequences is broader in scope than a chimeric polypeptide comprising operatively linked sequences, but the specification does not teach the metes and bounds of linked sequences. Specifically, do the functions of the individual elements that comprise a linked polypeptide need to be maintained as they are in an operatively linked chimeric polypeptide, or are other functional properties required of chimeric polypeptides comprising linked polypeptides? If the later, what are these properties?

Claim Objections

11. Claims 59, 62, 63, and 66 are objected to as comprising minor informalities. Specifically, claim 59 is objected to because it should recite either "a" or "one" between the worlds least and peptide in the first line of the claim. Clams 62, 63, and 66 depend from 59 but do not correct its deficiencies.

Specification

12. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the

sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. 131 and 132.

Specifically, it is noted that some of the Brief Description of the Figures indicate the SEQ ID number of the peptide(s) used in a particular experiment as well as the name of the peptide, while others indicate only the peptide name. The specification does teach in paragraph 42 how the named peptides of the invention correspond to SEQ ID numbers in the sequence list (such as the dnaJ 174 peptide being SEQ ID NO:4), but in the interest of completeness, consistency, and readability, applicant should amend the figure legends such that they all disclose the SEQ ID numbers of the peptides used in that particular experiment. Such an amendment is appropriate for the legends of Figures 3-5 and 19-25 which currently do not provide the SEQ ID numbers of the peptides used in the experiments.

Further, inspection of the sequence listing indicates that The Regents of the University of California are listed as inventors of the instant application. The Regents of the University of California are not listed as inventors on the oath and declaration, and further patents are granted to individuals, not institutions. The applicant information in field <110> of the sequence listing is a mandatory item as per MPEP 2424.02, and as such correction is required.

13. Claims 57 and 74 are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
June 13, 2006

6/21/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No. 10/001,938	Applicant(s) Albani et al.	
	Examiner Szperka, Michael	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See Office Action

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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